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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,462	08/14/2006	Yukiko Inamoto	2006_1261A	7229
513 7590 08/29/2008 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021				
EXAMINER				
RAO, SAVITHA M				
ART UNIT		PAPER NUMBER		
1614				
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08/29/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/589,462

**Applicant(s)**

INAMOTO ET AL.

**Examiner**

SAVITHA RAO

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 08/14/2006 and 11/13/2006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

Claims 1-3 are pending and are subject of this office action.

### ***Information Disclosure Statement***

Receipt is acknowledged of the Information Disclosure Statement filed on 08/14/2006 and 11/13/2006. The Examiner has considered the reference cited therein to the extent that each is a proper citation. Please see the attached USPTO Form 1449.

. The "Foreign patent documents "3-72426 and 64-3123" on 1449 dated 11/13/2006 has been lined out since an English translation of the two patent documents have not been provided.

### ***Claim Rejections - 35 USC § 102(b)***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Konishi et al (EP 0784975 referenced in the IDS) as evidenced by Reller (US 4219548).

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Konishi et al. discloses a drug for the treatment of skin injuries, particularly hardly curable diseases such as bedsore, which comprises as an active ingredient acetylsalicylic acid and the drug is used in the form of a topical preparation for external application (abstract, claims 1-4)). Konishi discloses that the topical preparation of his invention contains 0.05 to 15% by weight of acetylsalicylic acid bases on the whole weight of the preparation (page 3, lines 10-14, claim 3). Konishi discloses an example 1-10 which gives various topical formulations comprising acetylsalicylic acid ranging from 0.05% (example 8) to 15% (example 7) by weight (page 4, line 10 to page 7, line 15). Konishi also discloses a method for the treatment of skin injuries, especially hardly curable diseases such as bedsore by applying a topical preparation comprising acetylsalicylic acid to the injured region of the skin (page 2, lines 47-50).

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Accordingly claims 1-3 are anticipated by Konishi et al.

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Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Inamoto et al (US 2003/0125308 an English equivalent of WO2001/047525, referenced in the instant IDS) as evidenced by Reller (US 4219548).

Inamoto discloses external preparations having an excellent antipruritic activity acetylsalicylic acid as an active ingredients and a method of treating pruritis by using said external preparations [0001]. Inamoto discloses that acetylsalicylic acid (aspirin) has a strong analgesic activity, antifebrile activity and an antirheumatic activity being less on its side effects and superior in its safety [0006]. Inamoto also discloses that a new use of acetylsalicylic acid in the form of an external preparation, ointments for treating neuralgia and external preparations for treating skin injury and a transdermal administration system for treatment of thrombosis and prophylactic treatment of cancer has been illustrated in prior art [0008]. Inamoto discloses that the amount of acetyl salicylic acid in the external preparation depends on form of the preparation bus is 0.05-80%, preferably 0.05-70%, ,more preferably 0.1-50% per total amount by weight. Inamoto additionally discloses that if the aspirin amount is greater than 80% by weight, it is impossible to maintain the physical property of an external preparation and when it is less than 0.05% by weight, there is not enough antipruritic activity and therefore the amount of more than 80% or less than 0.05% is not preferable [0014]. Inamoto further provides examples of external formulations comprising acetylsalicylic acid (examples 1-25, Tables 1-4, [0027-0030]). Inamoto finally teaches that the preparation as per his invention is applied to the lesion [0025].

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Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain. Accordingly claims 1-3 are anticipated by Inamoto et al.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being as being unpatentable over Mizobuchi et al. (US 6268355 B 1) as evidenced by Reller (US 4219548).

Mizobuchi discloses a stable external preparation consisting essentially of acetylsalicylic acid and carriers (i.e., white vaseline, yellow vaseline, lanolin, purified bee wax, cetanol, steryl alcohol, stearic acid, hydrogenated oil, hydrocarbon gel, polyethylene glycol, liquid paraffin and squalane), wherein said preparation is formulated in the form of cataplasms, plasters, ointments, creams, external powders (col.3, line 30 to col.4 lines 43 and examples 1-32) and the amount of aspirin as an active ingredient in an external preparation is 0.001 to 30% by weight per total amount, preferably 0.01 to 20% by weight, more preferably 0.05 to 15% by weight (column 2, lines 15-26 and 58-60;). Mizobuchi teaches that said composition is superior in stability and transdermal absorption

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from skin (column 2, lines 6-10 and 61-65; column 12, lines 65-67); and that said composition having anti-inflammatory antipyretic analgesic is useful in enhancing healing of skin injury (Figure 1 and Experiment 4).

Reller is being provided as a supplemental reference to demonstrate the routine knowledge in using acetylsalicylic acid as active ingredient in topical composition that is useful for the treatment of inflammation of skin including dermatoses accompanied by inflammation, skin injury, contact burns and insect bites (see column 1, lines 18-43; column 1, line 66 through column 2, line 3; Example I-II). Particularly, Example II teaches that topical administration of aspirin is useful in reducing inflammation and the sensation of itching and pain.

Accordingly claims 1-3 are anticipated by Mizobuchi et al.

Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being as being unpatentable over Steen et al. (Pain 64(1996) 71-82).

Steen discloses the effectiveness and mechanisms of topically applied acetylsalicylic acid (ASA) among other anti-inflammatory agents (page 71, right col., 1st paragraph). Steen discloses that with a new route of administration, a topical application using Vaseline/paraffin as a vehicle, it was demonstrated that ASA and its metabolite salicylic acid block cutaneous pain from low pH dose-dependently and almost equally effectively (page 78, right column, 1<sup>st</sup> paragraph under "Discussion") .

Accordingly claims 1 and 3 are anticipated by Steen et al.

***Conclusion***

Claims 1-3 are rejected. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7 am to 4 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached at 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/  
Examiner, Art Unit 1614



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/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614